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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/666,689 | 09/19/2003 | James Lee | P0706P2C2D2C1 | 2217 |
| 9157 | 7590 | 04/06/2007 | EXAMINER | |
| GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080 | | | ULM, JOHN D | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1649 | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/06/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|---------------------------|--------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/666,689 John D. Ulm | LEE ET AL. Art Unit 1649 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 January 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 20-25,27,29 and 30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 20-25,27,29 and 30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1) Claims 20 to 25, 27, 29 and 30 are pending in the instant application. Claims 20 to 25 and 27 have been amended and claims 26, 28 and 31 to 73 have been canceled as requested by Applicant in the correspondence filed 10 January of 2007.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 January of 2007 has been entered.

Claim Rejections - 35 USC § 101

5) Claims 20 to 25, 27, 29 and 30 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 3 of the office action mailed 14 October of 2005. As stated therein, the instant claims are drawn to an isolated "PF4AR" protein that lacks a specific and substantial utility in currently available form because the instant application does not disclose a specific biological role for this

protein or its significance to a particular disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect.

In the response filed 10 January of 2007, Applicant has traversed this rejection on the basis that "experimental evidence of a specific and credible utility is not necessary" and that "no further experimentation is necessary in order appreciate that the claimed polypeptides are useful in the inflammatory cascade". The original rejection is based upon the fact that there is no actual evidence that the agonist activation of a putative receptor protein of the instant invention induces a specific inflammatory response from cells expressing it, the fact that there is no evidence that the exogenous administration of that protein or any other member of the chemokine receptor family to an individual induces an inflammatory response, and the fact that the instant specification fails to provide the critical information that would be needed by one of ordinary skill in the art to produce an antagonistic antibody to that protein. Applicant is advised that a statement of a specific utility is treated as credible only if it would be believed to be true by one of ordinary skill in the art given the evidence of record. Because there is absolutely no evidence provided by the instant specification or the prior art of record that the exogenous administration or agonist activation of a receptor protein of the instant invention actually induces an inflammatory response, the utilities asserted in the first full paragraph on page 4 of the instant specification are not credible to one of ordinary skill in the art of receptor biology in view of the evidence of record, or more precisely, the lack thereof.

Applicant's position that the USPTO is obligated to unquestionably accept any and all statements of fact in a patent application, irrespective of whether those statements are supported by any facts of record or sound scientific reasoning is erroneous. "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant 's assertions", (M.P.E.P. 2106.02 II(b)(1)(ii)).

Applicant's position that "the Examiner is essentially saying that Applicants must teach and disclose a ligand in order to establish a utility for the claimed receptor" and that "the Examiner is essentially arguing that Applicants must not only teach a utility for the disclosed polypeptide, but also for those polypeptide which interact with it" is factually incorrect. Applicant has urged, specifically in the Lee declaration filed 14 May 2006, that a protein of the instant invention is useful in the identification of antagonists thereto and that such antagonists would be expected to have anti-inflammatory activity. Applicant is advised that an antagonist to a chemokine receptor would be defined as any compound that inhibits the agonist-induced activity of that receptor. A chemokine receptor is recognized in the art as essentially any G protein-coupled receptor that is activated by a chemokine. Before one can identify an antagonist of a chemokine receptor, one must be capable of activating that receptor, and this usually requires one to know the identity of at least one compound that activates that receptor. Because the instant specification fails to provide the guidance needed to activate the putative chemokine receptor protein described therein without first making the substantial

inventive contribution of discovering the identity of at least one compound possessing the required agonistic activity, the claimed protein is not useful in the identification of anti-inflammatory compounds in its currently available form. As stated in the previous office action, It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),.

The claimed polypeptide lacks a specific and substantial utility in currently available form because there is no evidence that the exogenous administration of that protein induces an inflammatory response, because Applicant has failed to identify any particular situation where the induction of an inflammatory response would be desirable, and because the instant specification fails to provide that information that would be required to employ the claimed polypeptide in its currently available form in a process of identifying compounds having anti-inflammatory activity.

Claim Rejections - 35 USC § 112

6) Claims 20 to 25, 27, 29 and 30 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

Response to Arguments

7) Applicant's arguments filed 10 January of 2007 have been fully considered but they are not persuasive for those reasons given above.

Conclusion

Art Unit: 1649

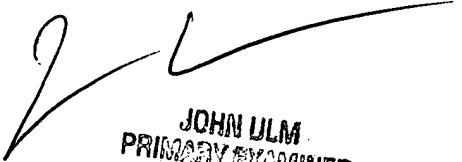
8) This is a continuation of applicant's earlier Application No. 10/666,689. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
GROUP 1800